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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,796	06/20/2000	Yasir Skeiky	014058-009050US	6269

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EXAMINER
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SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/597,796

Applicant(s)

SKEIKY ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27December2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 55-67 is/are pending in the application.
- 4a) Of the above claim(s) 67 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 64-66 is/are allowed.
- 6) ☒ Claim(s) 1-15 and 55-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-15,55-67 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 27December2004, is acknowledged.

Claims 6, 55, 63, and 64 have been amended. New claims 65-67 have been added.

Claims 1-15 and 55-67 are pending. Newly added claim 67 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Newly added claim 67 would not have been included in the originally elected invention I because the claim is drawn to a method of immunization using polypeptide.

2. Claims 1-15 and 55-66 are under consideration.

### **Rejections Withdrawn**

3. The rejection of claim 64 under 35 U.S.C. 112, second paragraph, indefiniteness, is withdrawn in light of the amendment of the claim.

4. The rejection of claims 55 and 61 under 35 U.S.C. 112, second paragraph, indefiniteness, is withdrawn in light of the claim amendments.

5. The provisional rejection of claims 1-5 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending App. No. 10/359,460 is withdrawn in light of the cancelation of claim 1 of copending App. No. 10/359,460.

6. The provisional rejection of claims 1-4, 6, and 62 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending App. No. 10/359,460 is withdrawn in light of the cancelation of claim 1 of copending App. No. 10/359,460.

### **Rejections Maintained**

7. The rejection of claims 1-4, 6, and 62 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Pat. No. 6,544,522 is maintained for reasons of record.

Applicants state that they will gladly consider filing a terminal disclaimer once the Examiner indicates that all pending claims are otherwise allowable.

The examiner has considered applicants statement, but maintains the rejection until such time as an appropriate Terminal Disclaimer has been received.

8. The provisional rejection of claims 1-5 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending App. No. 09/886,349 is maintained for reasons of record.

Applicants argue that, according to the MPEP, if a provisional double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent.

The examiner has considered applicants statement, but maintains the rejection until such time as the current rejection is the only rejection remaining in the application. At this time, there are other remaining rejections. It is noted by the examiner that claim 1 of copending App. No. 09/886,349 has been amended to now recite a new critical concerning substitution of various amino acids. This is but one embodiment. Claims 1-5 of copending App. No. 09/886,349 retain an embodiment which maintains the obviousness-type double patenting issue, i.e., both sets of claims are drawn to composition comprising immunogenic fragments.

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9. The provisional rejection of claims 1-4, 6, and 62 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 6 of copending App. No. 09/886,349 is maintained for reasons of record.

Applicants argue that, according to the MPEP, if a provisional double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent.

The examiner has considered applicants statement, but maintains the rejection until such time as the current rejection is the only rejection remaining in the application. At this time, there are other remaining rejections. It is noted by the examiner that claim 1 of copending App. No. 09/886,349 has been amended to now recite a new critical concerning substitution of various amino acids. This is but one embodiment. Claims 1-4 and 6 of copending App. No. 09/886,349 retain an embodiment which maintains the obviousness-type double patenting issue, i.e., both sets of claims are drawn to composition comprising immunogenic fragments.

10. The rejection of claims 6 and 56-60 under 35 U.S.C. 112, second paragraph, indefiniteness, is maintained for reasons of record.

Applicants argue that the amendment of claim 6 obviates the rejection.

The examiner has considered applicants' argument, but does not find it persuasive. While the amendment does restrict the template DNA as being the complement of the nucleotide sequence of MTB72F (SEQ ID NO:11), the indefiniteness remains due to the recitation that the conditions are merely "stringent" without any recitation of the actual stringency conditions or that the stringency is "high" with the actual conditions constituting high stringency being explicitly stated. Thus, the polynucleotide encoding the claimed fusion

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polypeptide composition remains unclear because an encoding polynucleotide of unknown proteins may bind to the complement template if the conditions of stringency are "low". It is recommended that the actual stringency conditions be recited in the claims.

11. The rejection of claim 63 under 35 U.S.C. 112, second paragraph, indefiniteness, is maintained for reasons of record.

Applicants argue that the amendment of claim 63 obviates the rejection.

The examiner has considered applicants' argument, but does not find it persuasive. While the amendment does restrict the template DNA as being the complement of the nucleotide sequence of MTB72F (SEQ ID NO:11), the indefiniteness remains due to the recitation that the conditions are merely "stringent" without any recitation of the actual stringency conditions or that the stringency is "high" with the actual conditions constituting high stringency being explicitly stated. Thus, the polynucleotide encoding the claimed fusion polypeptide composition remains unclear because an encoding polynucleotide of unknown proteins may bind to the complement template if the conditions of stringency are "low". It is recommended that the actual stringency conditions be recited in the claims.

12. The rejection of claims 7-15 under 35 U.S.C. 112, second paragraph, indefiniteness, is maintained for reasons of record.

Applicants argue that all relevant claims have been amended to overcome the indefiniteness rejections and therefore this rejection is also addressed.

The examiner has considered applicants' argument, but does not find it persuasive because the claims from which 7-15 depend remain rejected.

#### **New Rejections Necessitated by Amendment**

### **Claim Rejections - 35 USC § 112**

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 55 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 55 and 61 depend from rejected claims.

### **Conclusion**

15. Claims 1-15 and 55-63 are finally rejected. Claims 64-66 appear to be free of prior art following a sequence search for SEQ ID NO:12.

16. This application contains claim 67 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

17. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


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18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

April 6, 2005